IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Wilson et al.	)	
			)	Examiner:
Serial No.	:	10/790,943	)	James D. Anderson
			)	
Cnfrm. No.	:	2176	)	Art Unit:
			)	1614
Filed	:	March 2, 2004	)	
			)	
For	:	ANTI-CANCER COMBINATIONS	)	
			)	

PETITION UNDER 37 C.F.R. § 1.182
FOR THE WITHDRAWAL OF THE RECORDED TERMINAL DISCLAIMER
IN U.S. PATENT APPLICATION SERIAL NO. 10/790,943

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.182, Applicants respectfully request withdrawal of the Terminal Disclaimer that was filed in the above-identified application (U.S. Serial No. 10/790,943) on October 11, 2007. As set forth more fully below, the provisional nonstatutory obviousness-type double patenting rejection that prompted the filing of the Terminal Disclaimer is now rendered ***moot***. Therefore, Applicants respectfully submit that nullification of the Terminal Disclaimer is appropriate at this time.

On June 11, 2007, the U.S. Patent and Trademark Office ("USPTO") issued a Final Office Action in the present application (U.S. Serial No. 10/790,943). The Final Office Action included a ***provisional*** nonstatutory obviousness-type double patenting rejection of claims 1-4, 7, 8, 11-13, 16, 17, 20, and 21 of the present application over claims 1-23 of co-pending U.S. Patent Application Serial No. 11/592,678 (the "co-pending '678 Application"). The co-pending '678 Application is a continuation of the present application.

On October 11, 2007, Applicants filed a "Response" to the Final Office Action. Accompanying the Response was a "Terminal Disclaimer to Obviate a Provisional Double Patenting Rejection Over a Pending 'Reference' Application," which Applicants filed simply to dispense with the provisional nonstatutory obviousness-type double patenting rejection.

On October 31, 2007, Applicants filed a "Preliminary Amendment" in the co-pending '678 Application. A copy of this Preliminary Amendment is attached hereto as **Exhibit A**. By way of the Preliminary Amendment, Applicants amended the claims of the co-pending '678 Application in such a way as to render ***moot*** the provisional nonstatutory obviousness-type double patenting rejection previously made against the claims of the present application.

In particular, while the claims of the present application are limited to combinations of DMXAA and "gemcitabine," the claims of the co-pending '678 Application are now limited to the ***distinct*** combinations of DMXAA and "topoisomerase I inhibitor" generically and, more specifically, the particular topoisomerase I inhibitor "irinotecan." As disclosed in the present application (*see, e.g.,* page 9, line 14; page 12, lines 17-19), gemcitabine is an "antimetabolite." It is well known in the field of cancer therapeutics that antimetabolites (e.g., gemcitabine) and topoisomerase I inhibitors (e.g., irinotecan) belong to separate and distinct classes of compounds.

Under Federal patent law, a nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claims, because the examined application claim is either anticipated by, or would have been obvious over, the reference claims. Manual of Patent Examining Procedure (MPEP) § 804, at 800-21 (8th edition, Rev. 5) (August 2006); *see, e.g., In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

As indicated in the Final Office Action (at page 10), the subject double patenting rejection is dependent on the claims of both the present application and the co-pending '678 Application reciting the combination of DMXAA and "gemcitabine." However, because the claims of the co-pending '678 Application have now been amended to delete any reference to "gemcitabine" or even to the more generic "antimetabolite" class of compounds to which gemcitabine belongs, all claims in the present application and in the co-pending '678 Application are patentably distinct.

Therefore, because the provisional double patenting rejection has now been rendered moot due to the amendments to the claims of the co-pending '678 Application, the appropriate and equitable result is to grant Applicants' request to withdraw the Terminal Disclaimer.

Applicants further note that this Petition for withdrawal of the recorded Terminal Disclaimer in the present application is fully supported by MPEP § 1490, at 1400-115 to 1400-116. Consistent with MPEP § 1490, this Petition is appropriate to encourage the orderly administration of the examination process in both the present application and in the co-pending '678 Application.

Further, as the amendments to the claims of the co-pending '678 Application demonstrate, this Petition is not being filed merely to seek to reopen the question of the propriety of the provisional obviousness-type double patenting rejection that prompted the filing of the Terminal Disclaimer. Instead, it is clear from the record that the USPTO's entire basis for issuing the provisional double patenting rejection is due to the previously overlapping subject matter, i.e., the recitation of "gemcitabine" or "antimetabolites" in the claims of both applications at issue. Now that such overlapping subject matter ***does not exist*** between the two applications, there is no question that the double patenting rejection is improper.

In view of all of the foregoing, on the basis of this Petition, Applicants respectfully request that the USPTO nullify and withdraw the earlier filed Terminal Disclaimer for the present application.

Pursuant to 37 C.F.R. § 1.17(f), Applicants submit herewith the **$400.00** fee for this Petition,. The Commissioner is hereby authorized to charge any additional fees that may have been overlooked by Applicants to **Deposit Account No. 10-0223**.

Respectfully submitted by,

/Andrew K. Gonsalves/

Dated: **October 31, 2007**

Andrew K. Gonsalves, Esq.
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Exhibit A

Preliminary Amendment

Filed October 31, 2007
in
Co-Pending U.S. Patent Application Serial No. 11/592,678

(Printed from USPTO Public PAIR image file wrapper.)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Wilson et al.	Examiner: James D. Anderson
Serial No.	:	11/592,678	
Cnfrm. No.	:	3650	Art Unit: 1614
Filed	:	November 3, 2006	
For	:	ANTI-CANCER COMBINATIONS	

PRELIMINARY AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 7 of this paper.

LISTING OF CLAIMS

The following "Listing of the Claims" will replace all prior versions and all prior listings of the claims in the present application:

1. (Currently Amended) A method for treating cancer, which comprises administering to a mammal, in need of such treatment an effective amount of DMXAA or a pharmaceutically acceptable salt or ester thereof and administering an effective amount of ~~at least one of a compound selected from platinum compounds, vinca alkaloids, alkylating agents, anthracyclines,~~ a topoisomerase I inhibitor ~~inhibitors, antimetabolites and topoisomerase II inhibitors~~.

2. (Currently Amended) A method according to claim 1 wherein the DMXAA or pharmaceutically acceptable salt or ester thereof and the ~~at least one of a compound selected from platinum compounds, vinca alkaloids, alkylating agents, anthracyclines,~~ topoisomerase I inhibitor ~~inhibitors, antimetabolites and topoisomerase II inhibitors~~ are administered in a potentiating ratio.

3. (Currently Amended) A method according to claim 1 wherein the DMXAA or pharmaceutically acceptable salt or ester thereof and the ~~at least one of a compound selected from platinum compounds, vinca alkaloids, alkylating agents, anthracyclines,~~ topoisomerase I inhibitor ~~inhibitors, antimetabolites and topoisomerase II inhibitors~~ are administered concomitantly.

4. (Currently Amended) A method according to claim 1 wherein the DMXAA or pharmaceutically acceptable salt or ester thereof and the ~~at least one of a compound selected from platinum compounds, vinca alkaloids, alkylating agents, anthracyclines,~~ topoisomerase I inhibitor ~~inhibitors, antimetabolites and topoisomerase II inhibitors~~ are administered sequentially.

5. (Currently Amended) A method according to claim 1 or 2, wherein the ~~compound selected from platinum compounds, vinca alkaloids, alkylating agents, anthracyclines,~~ topoisomerase I inhibitor ~~inhibitors, antimetabolites and topoisomerase II inhibitors~~ is ~~a compound selected from carboplatin, gemcitabine, cisplatin, 5-fluorouracil, cyclophosphamide, etoposide, vincristine, doxorubicin and~~ irinotecan.

6. (Canceled)

7. (Currently Amended) A composition comprising a combination of DMXAA or a pharmaceutically acceptable salt or ester thereof and ~~at least one of a compound selected from platinum compounds, vinca alkaloids, alkylating agents, anthracyclines,~~ a topoisomerase I inhibitor ~~inhibitors, antimetabolites and topoisomerase II inhibitors~~.

8. (Currently Amended) A composition according to claim 7 wherein the DMXAA or a pharmaceutically acceptable salt or ester thereof and the ~~at least one of a compound selected from platinum compounds, vinca alkaloids, alkylating agents, anthracyclines,~~ topoisomerase I inhibitor ~~inhibitors, antimetabolites and topoisomerase II inhibitors~~ are present in a potentiating ratio.

9. (Currently Amended) A composition according to claim 7 or 8 wherein the ~~compound selected from platinum compounds, vinca alkaloids, alkylating agents, anthracyclines,~~ topoisomerase I inhibitor ~~inhibitors, antimetabolites and topoisomerase II inhibitors~~ is ~~a compound selected from carboplatin, gemcitabine, cisplatin, 5-fluorouracil, cyclophosphamide, etoposide, vincristine, doxorubicin and~~ irinotecan.

10. (Canceled)

11. (Currently Amended) A pharmaceutical formulation comprising a combination of DMXAA or a pharmaceutically acceptable salt or ester thereof and ~~at least one of a compound selected from platinum compounds, vinca alkaloids, alkylating agents, anthracyclines,~~ a topoisomerase I inhibitor ~~inhibitors, antimetabolites and topoisomerase II inhibitors~~ in association with one or more pharmaceutically acceptable carriers therefor.

12. (Original) A pharmaceutical formulation according to claim 11 wherein the formulation is adapted for intravenous administration.

13. (Currently Amended) A pharmaceutical formulation according to claim 11 or 12 wherein the DMXAA or pharmaceutically acceptable salt or ester thereof and the ~~at least one of a compound selected from platinum compounds, vinca alkaloids, alkylating agents, anthracyclines,~~ topoisomerase I inhibitor ~~inhibitors, antimetabolites and topoisomerase II inhibitors~~ are present in a potentiating ratio.

14. (Currently Amended) A pharmaceutical formulation according to claim 13 wherein the ~~compound selected from platinum compounds, vinca alkaloids, alkylating agents, anthracyclines,~~ topoisomerase I inhibitor ~~inhibitors, antimetabolites and topoisomerase II inhibitors is a compound selected from carboplatin, gemcitabine, cisplatin, 5-fluorouracil, cyclophosphamide, etoposide, vincristine, doxorubicin and~~ is irinotecan.

15. (Canceled)

16. (Currently Amended) A process for the preparation of a pharmaceutical formulation which process comprises bringing into association a combination of DMXAA or a pharmaceutically acceptable salt or ester thereof and ~~at least one of a compound selected from platinum compounds, vinca alkaloids, alkylating agents, anthracyclines,~~ a topoisomerase I inhibitor ~~inhibitors, antimetabolites and topoisomerase II inhibitors~~ with one or more pharmaceutically acceptable carriers therefor.

17. (Currently Amended) A process according to claim 16 wherein the DMXAA or pharmaceutically acceptable salt or ester thereof and the ~~at least one of a compound selected from platinum compounds, vinca alkaloids, alkylating agents, anthracyclines,~~ topoisomerase I inhibitor ~~inhibitors, antimetabolites and topoisomerase II inhibitors~~ are present in a potentiating ratio.

18. (Currently Amended) A process according to claim 16 or 17 wherein the ~~compound selected from platinum compounds, vinca alkaloids, alkylating agents, anthracyclines,~~ topoisomerase I inhibitor ~~inhibitors, antimetabolites and topoisomerase II inhibitors is a compound selected from carboplatin, gemcitabine, cisplatin, 5-fluorouracil, cyclophosphamide, etoposide, vincristine, doxorubicin and~~ is irinotecan.

19. (Canceled)

20. (Currently Amended) A kit comprising in association for separate administration DMXAA or a pharmaceutically acceptable salt or ester thereof and ~~at least one of a compound selected from platinum compounds, vinca alkaloids, alkylating agents, anthracyclines,~~ a topoisomerase I inhibitor ~~inhibitors, antimetabolites and topoisomerase II inhibitors~~.

21. (Currently Amended) A kit according to claim 20 wherein the DMXAA or pharmaceutically acceptable salt or ester thereof and the ~~at least one of a compound selected from platinum compounds, vinca alkaloids, alkylating agents, anthracyclines,~~ topoisomerase I inhibitor ~~inhibitors, antimetabolites and topoisomerase II inhibitors~~ are present in a potentiating ratio.

22. (Currently Amended) A kit according to claim 20 or 21 wherein the ~~compound selected from platinum compounds, vinca alkaloids, alkylating agents, anthracyclines,~~ topoisomerase I <u>inhibitor</u> ~~inhibitors, antimetabolites and topoisomerase II inhibitors is a compound selected from carboplatin, gemcitabine, cisplatin, 5-fluorouracil, cyclophosphamide, etoposide, vincristine, doxorubicin and~~ <u>is</u> irinotecan.

23. (Canceled)

REMARKS

Claims 1-5, 7-9, 11, 13, 14, 16-18, and 20-22 are hereby amended and claims 6, 10, 15, 19, and 23 are hereby canceled, so that claims 1-5, 7-9, 11-14, 16-18, and 20-22 are now currently pending in the present application.

After amendment, claims 1-4, 7, 8, 11-13, 16, 17, 20, and 21 are now limited to DMXAA or a pharmaceutically acceptable salt or ester thereof combined with a "topoisomerase I inhibitor." Support for these claims is found in the original claims and throughout the original specification (*see, e.g.*, page 11, line 23; page 12, line 6; page 14, lines 3, 6, 10, 14, 17, 20, and 23; and page 15, lines 2, 5, 8, 11, 14, and 18).

After amendment, claims 5, 9, 14, 18, and 22 are now limited to the topoisomerase I inhibitor "irinotecan." Support for these claims is found in the original claims and throughout the original specification (*see, e.g.,* page 12, lines 2 and 10; page 13, lines 21-24; and page 15, line 15).

In view of the foregoing, Applicants respectfully request that the claims as hereby amended be considered for allowance.

Respectfully submitted by,

/Andrew K. Gonsalves/

Dated: **October 31, 2007**

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Electronic Acknowledgement Receipt

EFS ID:	2401906
Application Number:	11592678
International Application Number:	
Confirmation Number:	3650
Title of Invention:	Anti-cancer combinations
First Named Inventor/Applicant Name:	William R. Wilson
Customer Number:	29933
Filer:	Andrew K. Gonsalves
Filer Authorized By:	
Attorney Docket Number:	8654/2222
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The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 and 1.17	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1		20071031_Preliminary_Amendment_87792_355006US2.pdf	116086 6c98400ca4f0801ed3e1a09f42e7318d09e2793e	yes	7

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Preliminary Amendment	1	1
	Claims	2	6
	Applicant Arguments/Remarks Made in an Amendment	7	7

Warnings:					
Information:					
2	Fee Worksheet (PTO-06)	fee-info.pdf	8260 f2ce62f25eb0a771c021f73ba80fae78ea448da5	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	124346		

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.